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10/539,399	10/03/2006	Henry William Lupton	Q88694	4662

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EXAMINER	
PANI, JOHN	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,399	LUPTON, HENRY WILLIAM	
	Examiner	Art Unit	
	JOHN PANI	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51,52 and 54-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51,52 and 54-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 5/23/2008 have been fully considered but they are not persuasive. In response to Applicant's assertion that Osawa does not disclose a reinforcing means comprising an elongated reinforcing member located on one of the flat major surfaces of a distal portion, the Examiner respectfully disagrees and directs Applicant to Figures 5A-5C. The Applicant appears to have misunderstood the Examiner's interpretation of Osawa. In Fig. 5A, the "major flat surface" is being interpreted as the flat, visible surface of the flat, angled, fin-like portion in addition to the portion that cannot be seen because it is under the reinforcing member. The "reinforcing member" is being interpreted as the portion that extends radially from this fin, and appears above and below the fin in Fig. 5B and faces out from the page in Fig. 5C. The "opposite minor surfaces" are being interpreted as the surface of the fin facing out from the page in Fig. 5B. Regarding Applicant's assertion that providing a reinforcing member on the minor surfaces of the guide wire would not provide a benefit in terms of obtaining additional torsional rigidity, the Examiner notes that the "reinforcing member" of Osawa is located on the major flat surface. Furthermore, it appears that the Applicant is asserting the Osawa does not teach a distal portion terminating in its distal end in a guide portion. The Examiner respectfully disagrees and submits that the flat portion of the fin (that which is not angled and is denoted by a vertical line in Fig. 5C) is interpreted as the "guide portion" and that this portion could be shaped. Furthermore, it

is unclear to the Examiner why the structure depicted in Figs. 5A-5C would not provide additional torsional rigidity over a tip which does not possess a member running along its flat surface, and Applicant's arguments amount to a mere assertion which lacks persuasive evidence that this is the case. It is further unclear how the allegation that "Osawa is essentially concerned with providing a distal portion of a guide wire in which the flexibility of the distal portion gradually increases towards the distal end" is "in direct contrast with the guide wire of the present invention." The desired increases in torsional rigidity would be in reference to a device without the "reinforcing member" clearly depicted in Figs. 5A-5C, and a stated goal of varying flexibility along the device's length would not preclude obtaining an increase in torsional rigidity, whether recognized by Osawa or not, particularly because the device of Osawa includes the claimed "reinforcing member". In reference to Applicant's submission that Osawa would teach away from the invention, the Examiner submits (as detailed above and below) that Osawa anticipates the invention and that thus this point is moot.

Claim Objections

2. Claims 70 and 72 are objected to because of the following informalities:

In reference to Claim 70

In line 2 it is suggested to replace "the body" with –a body--.

In reference to Claim 72

In line 1 it is suggested to delete "respective".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 51, 52, 54-67, and 69-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 56 recites the limitation "the longitudinally extending edge" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 59 recites the limitation "the longitudinally extending edge" in line 5. There is insufficient antecedent basis for this limitation in the claim. Additionally it is unclear what structure "thereof" in line 5 is referring to. Claim 70 recites the limitation "distal end thereof" in line 6. It is unclear what structure the "distal end" is "thereof." Claim 75 recites the limitation "the longitudinally extending edge" in line 2. There is insufficient antecedent basis for this limitation in the claim. Additionally it is unclear what structure "thereof" in line 3 is referring to. Claim 76 recites the limitation "the longitudinally extending edge" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 51, 52 and 54-76 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. No. 7,083,577 to Osawa et al. ("Osawa").

8. Osawa teaches:

In reference to Claims 68 and 70

A guide wire (1) for use in a surgical or other procedure for accessing a remote site in the body of a human or animal subject (col. 1 lines 5-7), the guide wire defining a longitudinally extending axis (see Fig. 10), and terminating at one end in a proximal portion (proximal end in Fig. 10), and at an opposite end in a distal portion (23) for accessing the remote site, the distal portion being of rectangular transverse cross-section (see Fig. 5C) defining a pair of opposite major flat surfaces (the thin, flat surfaces that angle inward in Fig. 5B and are shown face on in Fig. 5C), joined by a pair of opposite minor surfaces (the top surface shown in Fig. 5B, and matching bottom surface), and terminating adjacent a distal end thereof in a guide portion (thin, central flat portion in Fig. 5), the guide portion being adapted to be shaped to a desired curved configuration for facilitating guiding of the guide wire into a branched vessel of the subject (see col. 7 lines 31-40), wherein a reinforcing means (raised sections 232) is provided on the distal portion for minimizing axial twisting of the distal portion between a proximal end of the distal portion and the guide portion thereof (see col. 4 lines 50-65), the reinforcing means comprising an elongated reinforcing member having a proximal

end (thicker end) and a distal end (thinner end) and being located on one of the flat major surfaces, and extending along at least a portion of the distal portion between the proximal end of the distal portion and the guide portion.

In reference to Claim 51

A guide wire as claimed in claim 70 (see above) in which the distal end of the reinforcing member is spaced apart (radially, see Figs. 5A-5B) from the distal end of the distal portion of the guide wire and defines with the distal end of the distal portion of the guide wire the guide portion thereof.

In reference to Claim 52

A guide wire as claimed in claim 70 (see above), in which the reinforcing member extends from the proximal end of the distal portion (see Figs. 5A-5C).

In reference to Claim 54

A guide wire as claimed in claim 703 (see above) in which the major flat surfaces of the distal portion define a central major plane located midway between the major surfaces, and the minor surfaces of the distal portion define a central minor plane located midway between the minor surfaces (see Figs. 5A-5C).

In reference to Claim 55

A guide wire as claimed in claim 70 (see above) in which one of the reinforcing members is located on each of the major flat surfaces (Figs. 5A-5C).

In reference to Claim 56

A guide wire as claimed in claim 54 (see above) in which the transverse distance of the longitudinally extending edge of the reinforcing members from the central major plane is substantially constant along the reinforcing means (see Fig. 5B).

In reference to Claim 57

A guide wire as claimed in claim 54 (see above) in which the reinforcing member extends parallel to the central minor plane (i.e. radially).

In reference to Claim 58

A guide wire as claimed in claim 54 (see above) in which the reinforcing member extends at an angle greater than zero degrees to the central minor plane (the raised surfaces have extensions at various non-zero angles with respect to the central minor plane).

In reference to Claim 59

A guide wire as claimed in claim 70 (see above) in which the reinforcing member defines opposite longitudinally extending sides (flat portions depicted in Fig. 5C), the opposite longitudinally extending sides of the reinforcing member terminating along the longitudinally extending edge thereof (the distal tip is an edge longitudinally extended from the distal portion, see Fig. 5C).

In reference to Claim 60

A guide wire as claimed in claim 59 (see above) in which the opposite longitudinally extending sides of the reinforcing member are parallel to each other (see Fig. 5B).

In reference to Claim 61

A guide wire as claimed in claim 70 (see above) in which the reinforcing member is integrally formed with the distal portion (see Fig. 5A) of the guide wire.

In reference to Claim 62

A guide wire as claimed in claim 70 (see above) in which the distal portion of the guide wire extends through a sleeve (**3**), and a first securing means (**4**) at the distal end thereof secures the distal portion to the sleeve, the first securing means defining the distal end of the guide wire (see Fig. 10).

In reference to Claim 63

A guide wire as claimed in claim 62 (see above) in which the first securing means is shaped to form a dome shaped distal end (see Fig. 10) for facilitating passage of the guide wire smoothly through a vessel of the subject.

In reference to Claim 64

A guide wire as claimed in 62 (see above) in which the guide portion is located between the reinforcing member (see Fig. 5A) and the first securing means (The distal tip is melted to the securing means, thus the guide portion, which includes the flat portion as it extends across between the two reinforcing members would be between both of the reinforcing means, and portions of the securing means that were on either side of it, particularly when viewed head on from the distal end of the guidewire, see col. 7 lines 60-67 and Fig. 10).

In reference to Claim 65

A guide wire as claimed in claim 62 (see above) in which the first securing means comprises a solder joint, an adhesive joint, or a brazed joint (see col. 7 lines 58-60).

In reference to Claim 66

A guide wire as claimed in claim 62 (see above) in which the sleeve extends beyond the proximal end of the distal portion along a portion of the guide wire (see Fig. 10), and that a proximal end of the sleeve is secured to the guide wire by a second securing means that comprises an adhesive joint, solder joint, or a brazed joint (see col. 7 lines 55-60).

In reference to Claim 67

A guide wire as claimed in claim 70 in which the guide wire is substantially torsionally rigid between the distal portion and the proximal portion of the guide wire for minimizing axial twisting of the guide wire between the proximal portion and the guide portion (see col. 4 lines 50-65).

In reference to Claim 69

In combination a catheter (see col. 1 lines 5-7) and the guide wire as claimed in claim 70 (see above).

In reference to Claim 71

A guide wire as claimed in claim 70 (see above) in which the reinforcing member extends in a generally axial direction (see Fig. 5A).

In reference to Claim 72

A guide wire as claimed in claim 70 (see above) in which the major flat surfaces converge towards each other towards the distal end of the distal portion (see Fig. 5B).

In reference to Claim 73

A guide wire as claimed in claim 54 (see above) in which the reinforcing member coincides with the central minor plane (a plane running axially through the guide wire and perpendicular to the fins which form the major plane).

In reference to Claim 74

A guide wire as claimed in claim 70 (see above) in which the reinforcing member extends adjacent one of the minor surfaces (see Fig 5A).

In reference to Claim 75

A guide wire as claimed in claim 59 (see above) in which the opposite longitudinally extending sides of the reinforcing member converge towards the longitudinally extending edge thereof for defining the longitudinally extending edge as a longitudinally extending ridge (viewed head-on from the distal end, the distal tip/edge presents as a ridge, and it is a surface longitudinally extended from the proximal portion).

In reference to Claim 76

A guide wire as claimed in claim 59 in which the longitudinally extending edge of the reinforcing member converges towards the distal portion adjacent the distal end of the reinforcing member (the distal edge is a one point of a continuum in which the raised section converges towards the distal end of the guide wire).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JP 8/20/08

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736